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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,684	07/14/2003	Marc B. Garnick	PPI-111	8447

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,684	GARNICK, MARC B.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) *2,3,5-10,24,34-35 and 37-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,4,11-23,25-33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-11-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III (claims 1, 4, 11-23, 25-33 and 36) drawn to a method of treating breast cancer using an LHRH antagonist and an estrogen receptor modulator that is raloxifene in the reply filed on 2-28-06 is acknowledged.

Applicants elected the LHRH antagonist of claim 19 as the species election. However, this was an improper election since the election was not to a species but a genus. A telephone call was made to Maria Zacharakis, on March 13, 2006 for a proper election of species. Applicants elected, as the species election, the LHRH antagonist of claim 21.

In order to advance prosecution, an art rejection on the species of claim 22 has also been made since this species was found during the search of the species of claim 21. Thus, claims 1, 4, 11-23, 25-33 and 36 have been examined in this application to the extent they read on the elected species of claim 21 and prior art found species of claim 22. Claims 2-3, 5-10, 24, 34-35 and 37-46 are withdrawn form consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 19-20 and 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 27-29, the dosage of is designated as □g/kg/day. It is unclear if the designation of the dosage should be in g/kg/day or some other denotation of weight.

Claims 19-20 recite that the I and J variables are Pro or an analogue thereof and Gly-NH2 or D-Ala-NH2-, or an analogue thereof, respectively. It is unclear what modification can be made to the amino acids to render them analogues. The specification does not define the modification that are inclusive as analogs to praline, D-alanine or Glycine.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4, 11-23, 25-33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garnick et al. (US 5,780,435) and Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment).

The claims are drawn to a method of treating breast cancer using an LHRH antagonist and an estrogen receptor modulator that is raloxifene.

Garnick et al. teach the use of LHRH antagonist for the treatment of prostate cancer (see abstract). The methods of the invention generally feature administration to a subject of an LHRH-R antagonist, in combination with a second therapy (see abstract and col. 2, lines 16-29). Garnick et al. teach that LHRH antagonist refers to a compound that inhibits the luteinizing hormone releasing hormone receptor such that release of luteinizing hormone is inhibited (see col. 2, lines 55-58). These include compound 3342 Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-N-Me-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 and Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 (see table 1 and col. 11, lines 1-4). This meets

the limitation of claim 21-22 of the instant application. The histamine release for this analog is 126 measured by ED.sub.50 for histamine release in a standard in vitro histamine release assay of at least 3 μg/ml, more preferably at least 5 μg/ml, and still more preferably at least 10 μg/ml) (see col. 3, lines 1-6). This meets the limitation of claims 13-15 of the instant application. The pharmaceutical formulations can include the LHRH-R antagonist is administered time release formulation, for example in a composition which includes a slow release polymer, or by depot injection (see col. 15, lines 45-50). For dosage, a therapeutically effective amount of an LHRH-R antagonist may vary according to factors such as the disease state, age, and weight of the individual, and the ability of the LHRH-R antagonist (alone or in combination with one or more combination drugs) to elicit a desired response in the individual. Dosage regimens may be adjusted to provide the optimum therapeutic response (see col. 15, lines 10-20). The reference further teaches although the methods of the invention are described in particular with application to the treatment of prostate cancer, it will be appreciated by the skilled artisan that these methods also can be applied to the treatment of other sex hormone-dependent cancers, such as ovarian cancer or breast cancer, in humans or animals of either sex. (see col. 14, lines 56-64). The difference between the prior art and the instant application is that the reference does not teach the use of raloxifene.

However, Cummings et al. teach that among postmenopausal women with osteoporosis, the risk of invasive breast cancer decrease by 76% during 3 years of treatment with raloxifene (see page 2189). Raloxifene reduced the risk of invasive estrogen receptor-positive breast cancer by 90% (see page 2192). The reference concludes that the treatment with raloxifene decreased the risk of newly diagnosed breast cancer in postmenopausal women who have osteoporosis and who have no prior history of breast cancer (see page 2196). Cauley et al. teach that in a 4 year trial, raloxifene decreased of incidence of all breast

cancer by 62% and invasive breast cancers by 72% compared with placebo (see page 129). The reduction was largely due to the high significant reduction in the invasive estrogen receptor positive breast cancer. The reference state that raloxifene was selected due to the concerns regarding estrogens and breast cancer.

It has been held that combination of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980); In re Susi, 169 USPQ 423, 426 (1971); In re Crockett, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore it would have been obvious to treat newly diagnosed breast cancer in postmenopausal women with raloxifene and LHRH antagonist because individually raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo and LHRH antagonist is effective in treating sex hormone-dependent cancers, such as ovarian cancer or breast cancer. Furthermore, Garnick et al. teach that the LHRH antagonist can be utilized in combination with a second agent. Thus, given the effectiveness of raloxifene against breast cancer, one would have been motivated to use raloxifene with the LHRH antagonist.

As for the dosages claimed, the MPEP states "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" See MPEP 2144.05. Here, Garnick et al. teach a therapeutically effective amount of an LHRH-R antagonist may vary according to factors such as the disease state,

age, and weight of the individual, and the ability of the LHRH-R antagonist (alone or in combination with one or more combination drugs) to elicit a desired response in the individual. Thus, it would have been obvious to optimize the dosage to the range which elicits the desired response in the individual.

4. Claims 1, 4, 11-23, 25-33 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garnick et al. (US6211153 or 6180609 or 6384017) and Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment).

The claims are drawn to a method of treating breast cancer using an LHRH antagonist and an estrogen receptor modulator that is raloxifene.

All of the Garnick et al. references teach the use of LHRH antagonist for the treatment of breast cancer (see the claims in all of the references). The methods of the invention generally feature administration to a subject of an LHRH-R antagonist, in combination with a second therapy (see abstract in all of the references). Garnick et al. teach that LHRH antagonist refers to a compound that inhibits the luteinizing hormone releasing hormone receptor such that release of luteinizing hormone is inhibited (see col. 2, lines 57-61 in 6211153, col. 2, lines 58-64 in 6180609, and paragraph bridging col. 2-3 in 6384017). These include compound Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-N-Me-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 and Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 (see col. 6, lines 20-25 in 6211153, Col 4, lines 40-51 in 6,180,609, and Col. 6, lines 20-28 in 6384017). This meets the limitation of claim 21-22 of the instant application. The histamine release for this analog is 126 measured by ED.sub.50 for histamine release in a standard in vitro histamine release assay of at least 3 μg/ml, more preferably at least 5 μg/ml, and still more preferably at least 10 μg/ml) (see claims in all of cited patents). This

meets the limitation of claims 13-15 of the instant application. The pharmaceutical formulations can include the LHRH-R antagonist is administered time release formulation, for example in a composition which includes a slow release polymer, or by depot injection (see col. 11, 1-25 in 6211153, col. 11, lines 11-30 in 6180609, and the paragraph bridging col. 10-11 in 6384017). For dosage, a therapeutically effective amount of an LHRH-R antagonist may vary according to factors such as the disease state, age, and weight of the individual, and the ability of the LHRH-R antagonist (alone or in combination with one or more combination drugs) to elicit a desired response in the individual. Dosage regimens may be adjusted to provide the optimum therapeutic response (see col. 10, lines 33-45 in 6211153, col. 10, lines 44-60 in 6180609, and col. 10, lines 30-45 in 6384017). The difference between the prior art and the instant application is that the reference does not teach the use of raloxifene.

However, Cummings et al. teach that among postmenopausal women with osteoporosis, the risk of invasive breast cancer decrease by 76% during 3 years of treatment with raloxifene (see page 2189). Raloxifene reduced the risk of invasive estrogen receptor-positive breast cancer by 90% (see page 2192). The reference concludes that the treatment with raloxifene decreased the risk of newly diagnosed breast cancer in postmenopausal women who have osteoporosis and who have no prior history of breast cancer (see page 2196). Cauley et al. teach that in a 4 year trial, raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo (see page 129). The reduction was largely due to the high significant reduction in the invasive estrogen receptor positive breast cancer. The reference state that raloxifene was selected due to the concerns regarding estrogens and breast cancer.

It has been held that combination of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980); In re Susi, 169 USPQ 423, 426 (1971); In re Crockett, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore it would have been obvious to treat newly diagnosed breast cancer in postmenopausal women with raloxifene and LHRH antagonist because individually raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo and LHRH antagonist is effective in treating sex hormone-dependent cancers, such as ovarian cancer or breast cancer. Furthermore, Garnick et al. teach that the LHRH antagonist can be utilized in combination with a second agent. Thus, given the effectiveness of raloxifene against breast cancer, one would have been motivated to use raloxifene with the LHRH antagonist.

As for the dosages claimed, the MPEP states "[g]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation" See MPEP 2144.05. Here, Garnick et al. teach a therapeutically effective amount of an LHRH-R antagonist may vary according to factors such as the disease state, age, and weight of the individual, and the ability of the LHRH-R antagonist (alone or in combination with one or more combination drugs) to elicit a desired response in the individual. Thus, it would have been obvious to optimize the dosage to the range which elicits the desired response in the individual.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 4, 11-21, 23, and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-9, 27-29 and 31-32 of U.S. Patent No. US 6211153 in view of Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment).

The claims are drawn to a method of treating breast cancer using an LHRH antagonist and an estrogen receptor modulator that is raloxifene.

Garnick et al. teach the use of LHRH antagonist for the treatment of breast cancer (see claim 6). The LHRH antagonist claimed include compounds Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-N-Me-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 and Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 (see claims 31-32). This meets the limitation of claim 21-22 of the instant application. The histamine release for this analog is 126 measured

by ED.sub.50 for histamine release in a standard in vitro histamine release assay of at least 3 μg/ml, more preferably at least 5 μg/ml, and still more preferably at least 10 μg/ml) (see claims 26-30). This meets the limitation of claims 13-15 of the instant application. The difference between the prior art and the instant application is that the reference does not teach the use of raloxifene.

However, Cummings et al. teach that among postmenopausal women with osteoporosis, the risk of invasive breast cancer decrease by 76% during 3 years of treatment with raloxifene (see page 2189). Raloxifene reduced the risk of invasive estrogen receptor-positive breast cancer by 90% (see page 2192). The reference concludes that the treatment with raloxifene decreased the risk of newly diagnosed breast cancer in postmenopausal women who have osteoporosis and who have no prior history of breast cancer (see page 2196). Cauley et al. teach that in a 4 year trial, raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo (see page 129). The reduction was largely due to the high significant reduction in the invasive estrogen receptor positive breast cancer. The reference state that raloxifene was selected due to the concerns regarding estrogens and breast cancer.

It has been held that combination of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980); In re Susi, 169 USPQ 423, 426 (1971); In re Crockett, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore it would have been obvious to treat newly diagnosed breast cancer in postmenopausal women with raloxifene and LHRH antagonist because individually raloxifene decreased of incidence of all breast

cancer by 62% and invasive breast cancers by 72% compared with placebo and LHRH antagonist is effective in treating sex hormone-dependent cancers, such as ovarian cancer or breast cancer.

6. Claims 1, 4, 11-21, 23, and 36 directed to an invention not patentably distinct from claims 6-9, 27-29 and 31-32 of commonly assigned U.S. Patent No. US 6211153 in view of Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment). Specifically for the reasons set forth in the previous paragraph.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 6211153, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

7. Claims 1, 4, 11-21, 23, and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 10, and 17-18 of U.S. Patent

No. US 6,384,017 in view of Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment).

The claims are drawn to a method of treating breast cancer using an LHRH antagonist and an estrogen receptor modulator that is raloxifene.

Garnick et al. teach the use of LHRH antagonist for the treatment of breast cancer (see claim 10). The LHRH antagonist claimed include compounds Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-N-Me-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 and Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 (see claims 17-18). This meets the limitation of claim 21-22 of the instant application. The histamine release for this analog is 126 measured by ED.sub.50 for histamine release in a standard in vitro histamine release assay of at least 3 μg/ml, more preferably at least 5 μg/ml, and still more preferably at least 10 μg/ml) (see claims 2-4). This meets the limitation of claims 13-15 of the instant application. The difference between the prior art and the instant application is that the reference does not teach the use of raloxifene.

However, Cummings et al. teach that among postmenopausal women with osteoporosis, the risk of invasive breast cancer decrease by 76% during 3 years of treatment with raloxifene (see page 2189). Raloxifene reduced the risk of invasive estrogen receptor-positive breast cancer by 90% (see page 2192). The reference concludes that the treatment with raloxifene decreased the risk of newly diagnosed breast cancer in postmenopausal women who have osteoporosis and who have no prior history of breast cancer (see page 2196). Cauley et al. teach that in a 4 year trial, raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo (see page 129). The reduction was largely due to the high significant reduction in the invasive estrogen

receptor positive breast cancer. The reference state that raloxifene was selected due to the concerns regarding estrogens and breast cancer.

It has been held that combination of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980); In re Susi, 169 USPQ 423, 426 (1971); In re Crockett, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore it would have been obvious to treat newly diagnosed breast cancer in postmenopausal women with raloxifene and LHRH antagonist because individually raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo and LHRH antagonist is effective in treating sex hormone-dependent cancers, such as ovarian cancer or breast cancer.

8. Claims 1, 4, 11-21, 23, and 36 directed to an invention not patentably distinct from claims 1-4, 10 and 17-18 of commonly assigned U.S. Patent No. US 6,384,017 in view of Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment). Specifically for the reasons set forth in the previous paragraph.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 6,384,017, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c),

either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

9. Claims 1, 4, 11-21, 23, and 36 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7, 14-16, and 19-20 of U.S. Patent No. US 6,180,609 in view of Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment).

The claims are drawn to a method of treating breast cancer using an LHRH antagonist and an estrogen receptor modulator that is raloxifene.

Garnick et al. teach the use of LHRH antagonist for the treatment of breast cancer (see claim 7). The LHRH antagonist claimed include compounds Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-N-Me-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 and Ac-D-Nal-4-Cl-D-Phe-D-Pal-Ser-Tyr-D-Asn-Leu-Lys(iPr)-Pro-D-Ala-NH_2 (see claims 19-20). This meets the limitation of claim 21-22 of the instant application. The histamine release for this analog is 126 measured by ED.sub.50 for histamine release in a standard in vitro histamine release assay of at least 3 μg/ml, more preferably at least 5 μg/ml, and still more preferably at least 10 μg/ml) (see claims 14-16). This meets the limitation of claims 13-15 of the instant application. The difference between the prior art and the instant application is that the reference does not teach the use of raloxifene.

However, Cummings et al. teach that among postmenopausal women with osteoporosis, the risk of invasive breast cancer decrease by 76% during 3 years of treatment with raloxifene (see page 2189). Raloxifene reduced the risk of invasive estrogen receptor-positive breast cancer by 90% (see page 2192). The reference concludes that the treatment with raloxifene decreased the risk of newly diagnosed breast cancer in postmenopausal women who have osteoporosis and who have no prior history of breast cancer (see page 2196). Cauley et al. teach that in a 4 year trial, raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo (see page 129). The reduction was largely due to the high significant reduction in the invasive estrogen receptor positive breast cancer. The reference state that raloxifene was selected due to the concerns regarding estrogens and breast cancer.

It has been held that combination of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Kerkhoven, 205 USPQ 1069, 1072 (CCPA 1980); In re Susi, 169 USPQ 423, 426 (1971); In re Crockett, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore it would have been obvious to treat newly diagnosed breast cancer in postmenopausal women with raloxifene and LHRH antagonist because individually raloxifene decreased of incidence of all breast cancer by 62% and invasive breast cancers by 72% compared with placebo and LHRH antagonist is effective in treating sex hormone-dependent cancers, such as ovarian cancer or breast cancer.

10. Claims 1, 4, 11-21, 23, and 36 directed to an invention not patentably distinct from claims 1, 7, 14-16, and 19-20 of commonly assigned U.S. Patent No. US 6,180,609 in view of

Cummings et al. (JAMA) or Cauley e et al. (Breast Cancer Research and Treatment). Specifically for the reasons set forth in the previous paragraph.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned US 6,180,609, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can normally be reached on (571) 272-0974. The fax phone number of this group is (571)-273-8300.

3/17/06

ANISH GUPTA
PRIMARY EXAMINER